

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S,

Plaintiff and Counterdefendant,

v.

AVENTIS PHARMACEUTICALS INC,
SANOFI-AVENTIS, and AVENTIS
PHARMA DEUTSCHLAND GMBH,

Defendants and Counterplaintiffs.

Case No. 05-645 (SLR)

**REDACTED
PUBLIC VERSION**

DECLARATION OF ANNE SHEA GAZA

I, Anne Shea Gaza, declare as follows:

1. I am a member of the Delaware Bar, an associate of the firm of Richards, Layton & Finger, P.A. and counsel for plaintiff Novo Nordisk A/S. I make this affidavit in support of Novo Nordisk A/S' Memorandum in Opposition to Aventis's Motion for Leave to File and Amended Answer and Counterclaims.

2. Attached hereto as Exhibit A is a true and correct copy of a November 1, 2006 letter from Eric Moran to Stephen Vitola;

3. Attached hereto as Exhibit B is a true and correct copy of documents bearing production numbers NN 034503 through NN 034505 [Notice of allowability];

4. Attached hereto as Exhibit C are true and correct copies of selected excerpts of the transcript of the deposition of Marc Began conducted on October 3, 2006;

5. Attached hereto as Exhibit D is a true and correct copy of an August 7, 2006 letter from Eric Moran to Stephen Vitola;

6. Attached hereto as Exhibit E is a true and correct copy of the selected excerpts from the file history of U.S. Patent No. 6,562,011 bearing production numbers SAN00762393 through SAN00762398 [produced in its entirety to SAN00762586];

7. Attached hereto as Exhibit F is a true and correct copy of an August 9, 2006 letter from Eric Moran to Stephen Vitola;

8. Attached hereto as Exhibit G is a true and correct copy of the front page of U.S. Patent No. 6,562,011 which was produced by Aventis bearing production numbers SAN00823009 through SAN00823014;

9. Attached hereto as Exhibit H is a true and correct copy of selected excerpts from the file history of U.S. Patent No. 6,562,011 bearing production numbers SAN00828212 through SAN00828405;

10. Attached hereto as Exhibit I is a true and correct copy of the front page of U.S. Patent No. 6,146,361 which was produced by Aventis bearing production numbers SAN00760915 through SAN00760923;

11. Attached hereto as Exhibit J is a true and correct copy of the front page of U.S. Patent No. 4,936,833 which was produced by Aventis bearing production numbers SAN00762258 through SAN00762270;

12. Attached hereto as Exhibit K is a true and correct copy of the front page of U.S. Patent No. 5,554,125 which was produced by Aventis bearing production numbers SAN00762354 through SAN00762372;

13. Attached hereto as Exhibit L is a true and correct copy of the front page of U.S. Patent No. 5,549,575 which was produced by Aventis bearing production numbers SAN00762343 through SAN00762353;

14. Attached hereto as Exhibit M is a true and correct copy of the front page of U.S. Patent No. 5,137,511 which was produced by Aventis bearing production numbers SAN00762289 through SAN00762307; and

15. Attached hereto as Exhibit N is a is a true and correct copy of a September 6, 2006 letter from James McCarthy to Stephen Vitola.

I DECLARE UNDER THE PENALTY OF PERJURY THAT THE ABOVE IS TRUE
AND CORRECT.

Date: November 22, 2006

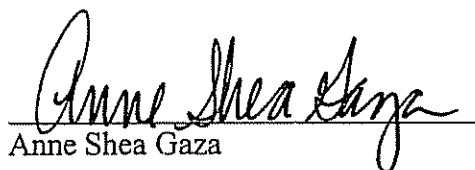

Anne Shea Gaza

EXHIBIT A

Nov-01-06 18:36

From: McDONNELL BOEHMEN HULBERT & BERGHOFF

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P-02

F-262



McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive
Chicago, Illinois 60606-6709
www.mbhb.com312 913 0001 phone
312 913 0002 fax

November 1, 2006

**VIA FACSIMILE
212 354 8113**Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036-2787Re: ***Novo Nordisk A/S v. sanofi-aventis et al.***
Civil Action No. 05-00645 SLR

Dear Steve:

Pursuant to Local Rule 7.1.1, please find enclosed Aventis's Second Consolidated and Amended Answer and Counterclaims. Aventis intends to file the attached pleading on Monday, November 6, 2006. Please advise before then whether you will consent to or oppose our motion for leave to file Aventis's Second Consolidated and Amended Answer and Counterclaims.

Please note that the attached pleading includes references and quotations from Marc Began's deposition. We do not believe these references or quotations include any confidential information; however, Novo designated Mr. Began's entire deposition transcript as highly confidential. Before November 6, 2006, please advise whether you would like us to file the attached pleading under seal. Please note, any motion for leave to amend that we will file regarding the attached pleading may include the same references and quotations from Mr. Began's deposition.

Regards,

A handwritten signature in black ink, appearing to read "Eric R. Moran", written over a horizontal line.

Eric R. Moran
312 913 3302 direct
moran@mbhb.com

Enclosure

EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20514
www.uspto.gov

APPLICATION NO.	FILED DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,741	07/06/1999	THOMAS DOCH-BASCHKESEN	5573.200-US	7085

28137 7598 85712082

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOW LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER

STIMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3783

DATE MAILED: 05/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-600 (Rev. 07-01)

NN 034503

NK

Notice of Allowability	Application No. 00/348,748 Examiner Kevin C. Birmons	Applicant(s) BUCH-RASMUSSEN ET AL Art Unit 3783
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- The MAILING DATE of this communication appears on the cover sheet with the correspondence address-
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
 herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS
 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
 of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/22/02.
2. ☒ The allowed claim(s) is/are 1-11.
3. ☒ The drawings filed on 1/19/02 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☒ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the
International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____

5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-848) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____
 - (b) ☐ Including changes required by the proposed drawing correction filed _____ which has been approved by the Examiner.
 - (c) ☐ Including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____

Identifying indicia such as the application number (see 37 CFR 1.54(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.
9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1 <input type="checkbox"/> Notice of References Cited (PTO-892) 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-848) 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ 6 <input type="checkbox"/> Examiner's Amendment/Comment 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9 <input type="checkbox"/> Other
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Application/Control Number: 09/349,748
Art Unit: 3763

Page 2

DETAILED ACTION

Allowable Subject Matter


Claims 34-44 are allowable over the prior art of record at the time the invention was made.

The following is an examiner's statement of reasons for allowance: Claims 34, 37, 43 and 44 are allowable over the prior art of record because the prior art does not disclose or render obvious the combination of a first or second coupling means which comprises a snap lock for assisting in coupling or uncoupling of a needle assembly from a cartridge by grasping the needle assembly and the dosage assembly simultaneously and applying force to both, thus preventing the cartridge assembly from moving axially with respect to the dosage assembly.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Simons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.


Kevin C. Simons
Patent Examiner
1/23/03



BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

EXHIBIT C

REDACTED
IN ITS
ENTIRETY

EXHIBIT D

Aug-07-06 17:27

From: MCDONNELL BOEHNNEN HULBERT & BERGHOFF

+13128130000Z

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P 02/03 F-736



McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive 312 913 0001 phone
Chicago, Illinois 60606-6709 312 913 0002 fax
www.mbh.com

August 7, 2006

VIA OVERNIGHT COURIER

Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036-2787

Re: **Novo Nordisk A/S v. sanofi-aventis et al.**
Civil Action No. 05-00645 SLR

Dear Steve:

Please find enclosed additional Aventis production documents and things. Because of the large number of documents in our production, we have provided these documents on an external USB hard drive. The USB hard drive is "plug and play" and no drivers or software should be required to access the files stored thereon.

We have included the following ranges of documents on the enclosed hard drive:
SAND0100001 through SAND0184310; SAND0300001 through SAND0327077;
SAND0200001 through SAND0255514; SAND0400001 through SAND0457077;
SAND0500001 through SAND0587677; SAND0700001 through SAND0764315; and load files. Please note the gaps in Bates numbers are intentional and were necessary in order to produce such a large number of documents at one time.

Aventis's CONFIDENTIAL and HIGHLY CONFIDENTIAL—OUTSIDE COUNSEL EYES ONLY documents are being produced pursuant to Local Rule 26.2 until a protective order is entered. Under Local Rule 26.2, disclosure of these documents should be limited to members and employees of Novo's outside trial counsel who have entered an appearance or have been admitted pro hac vice in this litigation. Aventis's HIGHLY CONFIDENTIAL documents shall not be shared with anyone at Novo at any time, under any circumstances.

Aug-07-06 17:27 From: MCDONNELL BOEHLEN HULBERT & BERGHOFF +131281300002 T-380 P. 03/03 F-736

The enclosed documents include the vast majority of our production documents. Due to the large number of documents in the current production, however, we will also be producing some additional documents in the next few days. As always, we will continue to supplement our production as more documents become available.

Regards,



Eric R. Moran
312 913 3302 direct
moran@mbhb.com

encl.

EXHIBIT E



REEDFAX
THE PATENT-EDMUNDSON GROUP

HOW THAT'S



United States Patent File History

Tab Listings

- A. References (if applicable)
 - A1-U.S. References
 - A2-Foreign References
- B. Jacket (face of file, contents flap, index of claims, PTO 270, searched)
- C. Printed Patent
- D. Specification (serial no. Sheet, abstract, specification, claims)
- E. Oath
 - E1-Small Entity Status (if applicable)
- F. Drawing Figures (if applicable)
- G. USPTO/Applicant Correspondence
- H. Original Patent Application (in cases of FWC)

Supplied by:

REEDFAX

117 Gibraltar Road, Horsham, PA 19044-0962

Customer Service: 1-800-422-1337 or 215-441-4768

Fax: 1-800-421-5585 or 215-441-5463

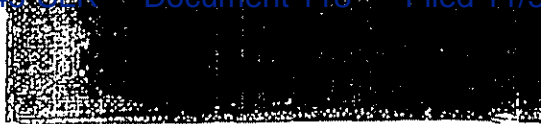
www.reedfax.com

 LexisNexis

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SAN00762393

604	232	Subclass
ISSUE CLASSIFICATION		



O.I.P.E.	PATENT DATE
DU40	MAY 13 2003
SCANNED <u>AGP</u>	

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	621	1	3-163 1-1	12/12/10

PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION									
ORIGINAL		CROSS REFERENCE(S)							
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<input type="checkbox"/> TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drawn <i>2</i>	Figs. Drawn <i>4</i>	Print Fig <i>1</i>	Total Claims <i>7</i>	Print Claim for O.G. <i>2</i>
<input type="checkbox"/> a) The term of this patent subsequent to _____ (date) has been disclaimed. <input type="checkbox"/> b) The term of this patent shall not extend beyond the expiration date of U S Patent No. _____ _____ _____	<i>Kurt C. Garrison</i> (Assistant Examiner) (Date)			NOTICE OF ALLOWANCE MAILED <i>9-20-02</i>	
	BRIAN L CASLER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700 <i>Brian L. Casler</i> (Primary Examiner) (Date) <i>9/15/02</i>			ISSUE FEE <i>46</i>	
				Amount Due <i>\$1280.00</i>	Date Paid <i>12-18-02</i>
<input type="checkbox"/> c) The terminal _____ months of this patent have been disclaimed.	<i>Green</i> (Legal Instruments Examiner) (Date) <i>9-25-02</i>			ISSUE BATCH NUMBER	
WARNING: The information disclosed herein may be restricted. Unauthorized disclosure may be prohibited by the United States Code Title 35, Sections 122, 161 and 388. Possession outside the U.S. Patent & Trademark Office is restricted to authorized employees and contractors only.					

Form FD-302 (Rev. 8-1-61)

ISSUE FREE IN FILE

CHANGES IN FILE

(LABEL AREA)

(FACE)

SAN00762394

PATENT APPLICATION



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JUL 18 2006 U.S. PAT. & TM. OFF.

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INITIALS MTW

CONTENTS

	Date received (Incl. C. of M.) or Date Mailed	Date received (Incl. C. of M.) or Date Mailed
1. Application _____ papers.		
2. Unsigned Dec	8/5/99	
3. Dec + Surcharge	10-12-99	
4. Pro Amal H	7.7.99	
5. Pro Amal H	7.7.99	
6. Alpha Backup	3/9/00	
7. Alpha Backup	4-4-00	
8. Alpha Backup	04/26/00 4-24/00	
9. Alpha Backup	2/7/00	
10. Reg. For C.F.R.	1/31/00	
11. Ext of Time (3)	10/27/00	
12. Final C.F.	10/27/00	
13. FINAL REJECT	10/17/01	
14. Ext of Time	6-13-01	
15. Reg. For Records	6-13-01	
16. REJECTION	6/27/01	
17. Notice of Appeal	6/19/01	
18. Ext of Time (1)	1/14/02	
19. Reg. For Records	1/14/02	
20. Reg. For Records	4/30/02 4/30/02	
21. Reg. For Records	8/20/02	
22. EXAMINATION	9-20-02	
23. QUERY	10/22/02 11/13/02 DE	
24. REG. FOR RECORD	11/13/02	
25. Priority	02-12-03	
26. 55B CHG. OF ADD	12/18/02	
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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	MA		7/14/99
O.P.E. CLASSIFIER	M-TW	5A	7-21-99
FORMALITY REVIEW	RF	70556	8-5-99
	RF	70556	10-20-99

INDEX OF CLAIMS

✓ Rejected
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N Non-elected
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 A Appeal
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Claim	Final	Original	Date
1			
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SAN00762396

SEARCHED			
Class	Sub.	Date	Exmr.
604	200-201 228 230-234	1/21/00	KCS
Same	as above	7/17/02	KCS

INTERFERENCE SEARCHED			
Class	Sub.	Date	Exmr.
Same as	above	9/17/02	KCS

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	Date	Exmr.
M. Bockelman	11/21/00	KCS

(RIGHT OUTSIDE)

SAN00762397

US006562011B1

(12) **United States Patent**
Buch-Rasmussen et al.(10) Patent No.: **US 6,562,011 B1**
(45) Date of Patent: **May 13, 2003**(54) **MEDICATION DELIVERY DEVICE**(75) Inventors: **Thomas Buch-Rasmussen, Gentofte (DK); Benny Munk, Hvidovre (DK); Jens Ulrik Poulsen, Virum (DK); Henrik Ljunggren, Ballerup (DK); Peter Møller Jensen, Hørsholm (DK); Jens Møller Jensen, Copenhagen (DK)**(73) Assignee: **Novo Nordisk A/S, Bagsvaerd (DK)**(*) Notice: **Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.**(21) Appl. No.: **09/348,536**(22) Filed: **Jul. 7, 1999****Related U.S. Application Data**

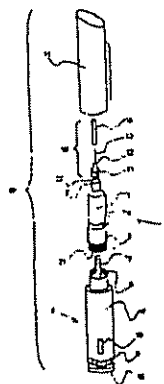
(60) Provisional application No. 60/098,702, filed on Sep. 1, 1998.

(30) **Foreign Application Priority Data**Jul. 8, 1998 (DK) 1998 00909
Nov. 17, 1998 (DK) 1998 01500(51) Int. Cl.⁷ **A61M 5/00**(52) U.S. Cl. **604/232**(58) Field of Search **604/200-201, 604/228, 232-234**(56) **References Cited****U.S. PATENT DOCUMENTS**4,597,753 A * 7/1986 Turkey 604/61
4,865,591 A * 9/1989 Sams 604/186
4,936,833 A 6/1990 Sams
4,973,318 A 11/1990 Holm et al.
5,137,511 A * 8/1992 Reynolds 604/68
5,226,895 A 7/1993 Harris
5,364,369 A * 11/1994 Reynolds 604/187
5,549,575 A 8/1996 Giambattista et al.5,554,125 A * 9/1996 Reynolds 604/187
5,688,251 A 11/1997 Chaoch
6,146,361 A * 11/2000 DiBiasi et al. 604/232**FOREIGN PATENT DOCUMENTS**EP 0 688 571 12/1995
WO WD 94/23213 9/1994
WO WD 95/13842 5/1995
WO WD 96/02290 2/1996
WO WD 97/49620 12/1997

* cited by examiner

Primary Examiner—Brian L. Casler**Assistant Examiner—Kevin C. Simmons**(74) Attorney, Agent, or Firm—**Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.**(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bayonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets

SAN00762398

EXHIBIT F

Aug-08-06 17:06

From=McDONNELL BOEHNNEN HULBERT & BERGHOFF

+13129130002

T-394

P.02/04

F-748



McDonnell Boennen Hulbert & Berghoff LLP

300 South Wacker Drive 312 913 0001 phone
Chicago, Illinois 60606-6709 312 913 0002 fax
www.mbhbb.com

August 9, 2006

VIA OVERNIGHT COURIER

Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, NY 10036-2787

Re: **Novo Nordisk A/S v. sanofi-aventis et al.**
Civil Action No. 05-00645 SLR

Dear Steve:

Please find enclosed additional Aventis production documents. The first two enclosed disks are DVD+R disks. The first DVD+R disk contains documents Bates numbered SAN00764316 through SAN00786484 and the second DVD+R disk contains documents Bates numbered SAN00786485 through SAN00822634 and load files. The third disk is a CD-ROM that contains documents Bates numbered SAN00822635 through SAN00836902 and load files and the fourth disk is a CD-ROM that contains documents Bates numbered SAN00836903 through SAN00837067 and load files.

Aventis's CONFIDENTIAL and HIGHLY CONFIDENTIAL—OUTSIDE COUNSEL EYES ONLY documents are being produced pursuant to Local Rule 26.2 until a protective order is entered. Under Local Rule 26.2, disclosure of these documents should be limited to members and employees of Novo's outside trial counsel who have entered an appearance or have been admitted pro hac vice in this litigation. Aventis's HIGHLY CONFIDENTIAL documents shall not be shared with anyone at Novo at any time, under any circumstances.

Due to the large number of documents in the current production, we will also be producing some additional documents tomorrow, and we currently believe that tomorrow's production will conclude our document production in this litigation. We will, however, supplement our production if more documents come to our attention.

Regards,

A handwritten signature in black ink, appearing to read "Eric R. Moran", written over a horizontal line.

Eric R. Moran
312 913 3302 direct
moran@mbhb.com

encls.

EXHIBIT G



US006562011B1

(12) **United States Patent**
Buch-Rasmussen et al.

(10) Patent No.: **US 6,562,011 B1**
 (45) Date of Patent: **May 13, 2003**

(54) **MEDICATION DELIVERY DEVICE**

(75) Inventors: Thomas Buch-Rasmussen, Gentofte (DK); Benny Munk, Hvidovre (DK); Jens Ulrik Poulsen, Virum (DK); Henrik Ljunggreen, Ballerup (DK); Peter Møller Jensen, Hørsholm (DK); Jens Møller Jensen, Copenhagen (DK)

(73) Assignee: Novo Nordisk A/S, Bagsvaerd (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/348,536

(22) Filed: Jul. 7, 1999

Related U.S. Application Data

(60) Provisional application No. 60/098,702, filed on Sep. 1, 1998.

(30) **Foreign Application Priority Data**

Jul. 8, 1998 (DK) 1998 00909
 Nov. 17, 1998 (DK) 1998 01500

(51) Int. Cl.⁷ A61M 5/00

(52) U.S. Cl. 604/232

(58) Field of Search 604/200-201, 604/228, 232-234

(56) **References Cited**

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5,554,125 A • 9/1996 Reynolds 604/187
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* cited by examiner

Primary Examiner—Brian L. Casler

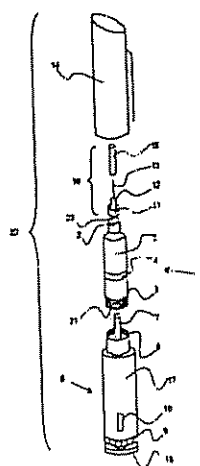
Assistant Examiner—Kevin C. Sirmons

(74) Attorney, Agent, or Firm—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bayonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets



SAN00823009

EXHIBIT H

United States Patent File History

Tab Listings

- A. References (if applicable)
 - A1-U.S. References
 - A2-Foreign References
- B. Jacket (face of file, contents flap, index of claims, PTO 270, searched)
- C. Printed Patent
- D. Specification (serial no. Sheet, abstract, specification, claims)
- E. Oath
 - E1-Small Entity Status (if applicable)
- F. Drawing Figures (if applicable)
- G. USPTO/Applicant Correspondence
- H. Original Patent Application (in cases of FWC)

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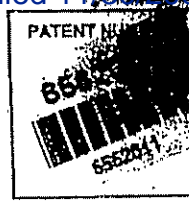
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604	232
Class	Subclass
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<p>O.I.P.E.</p> <p>DU4P</p> <p>SCANNED <u>AG Bar</u> <u>MT</u></p>	<p>PATENT DATE</p> <p>MAY 13 2003</p>
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ORIGINAL		CROSS REFERENCE(S)				
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<input type="checkbox"/> TERMINAL DISCLAIMER	DRAWINGS Sheets Drawn: <u>2</u> Figs. Drawn: <u>4</u> Print Fig: <u>2</u>			CLAIMS ALLOWED Total Claims: <u>7</u> Print Claim for O.G.: <u>2</u>	
				NOTICE OF ALLOWANCE MAILED <u>9-20-02</u>	
<input type="checkbox"/> a) The term of this patent subsequent to _____ (date) has been disclaimed. <input type="checkbox"/> b) The term of this patent shall not extend beyond the expiration date of U.S. Patent. No. _____	BRIAN L. CABLER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700 <u>Brian L. Cabler</u> 9/25/02 (Primary Examiner) (Date)			ISSUE FEE <u>98</u> Amount Due: <u>\$1280.00</u> Date Paid: <u>12-18-02</u>	
				ISSUE BATCH NUMBER	
<input type="checkbox"/> d) The terminal _____ months of this patent have been disclaimed. <u>36</u> months <u>9-25-02</u> (Date)					

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ISSUE FEE IN FILE

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PATENT APPLICATION



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INITIALS M.T.W.

CONTENTS

	Date received (Incl. C. of M.) or Date Mailed	Date received (Incl. C. of M.) or Date Mailed
1. Application _____ papers.		42. _____
2. Unsigned Dec	8/5/99	43. _____
3. Dec + Surcharge	10-12-99	44. _____
4. Pro Amend A	7.7.99	45. _____
5. Pro Amend B	7.7.99	46. _____
6. Pro Amend C	3/9/00	47. _____
7. Pro Amend D	4-9-00	48. _____
8. Pro Amend E	04/26/00	49. _____
9. Pro Amend F	2/7/00	50. _____
10. Reg For CER	1/31/00	51. _____
11. Ext of Time (3)	10/27/00	52. _____
12. Final Rejection	10/27/00	53. _____
13. Final Rejection	10/27/00	54. _____
14. Reg For Records	6-12-01	55. _____
15. Reg For Records	13-11	56. _____
16. REJECTION	6/27/01	57. _____
17. Notice of Appeal	6/18/01	58. _____
18. Ext of Time (1)	1/14/02	59. _____
19. Reg For Records	1/14/02	60. _____
20. Reg For Records	4/30/02	61. _____
21. Reg For Records	8/20/02	62. _____
22. Examination Amendment	9-20-02	63. _____
23. QUERY	10/22/02	64. _____
24. REG PURCHUR	11/13/02	65. _____
25. Priority	02-12-03	66. _____
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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION	<i>ME</i>		7/14/99
O.I.P.E. CLASSIFIER	<i>M-TW</i>	51	7/21/99
FORMALITY REVIEW	<i>RE</i>	70556	8-5-99
	<i>RE</i>	70556	10-20-99

INDEX OF CLAIMS

✓ Rejected
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 + Canceled
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N Non-elected
 I Interference
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 O Objected

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1	1/2/00
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NEET INSIDE

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SEARCHED			
Class	Sub.	Date	Exmr.
604	200-201 228 232-234	11/21/00	KCS
Same	as above	7/17/02	KCS

INTERFERENCE SEARCHED			
Class	Sub.	Date	Exmr.
Same as	above	7/17/02	KCS

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	Date	Exmr.
M. Bockelman	11/21/00	KCS

(RIGHT OUTSIDE)

SAN00828216

(12) **United States Patent**
Buch-Rasmussen et al.

(10) Patent No.: **US 6,562,011 B1**
 (45) Date of Patent: **May 13, 2003**

(54) **MEDICATION DELIVERY DEVICE**

(75) Inventors: **Thomas Buch-Rasmussen, Gentofte (DK); Benny Muck, Hvidovre (DK); Jens Ulfik Poulsen, Virum (DK); Henrik Ljunggren, Ballerup (DK); Peter Møller Jensen, Herlev (DK); Jens Møller Jensen, Copenhagen (DK)**

(73) Assignee: **Novo Nordisk A/S, Bagsvaerd (DK)**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/348,536**

(22) Filed: **Jul. 7, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/098,702, filed on Sep. 1, 1998.

Foreign Application Priority Data

Jul. 8, 1998 (DK) 1998 00909
 Nov. 17, 1998 (DK) 1998 01500

(51) Int. Cl.⁷ **A61M 5/00**

(52) U.S. Cl. **604/232**

(58) Field of Search **604/200-201, 604/228, 232-234**

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 WO 97/49620 12/1997

* cited by examiner

Primary Examiner—Brian L. Casler
 Assistant Examiner—Kevin C. Simons

(74) Attorney, Agent, or Firm—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) ABSTRACT

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bayonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets

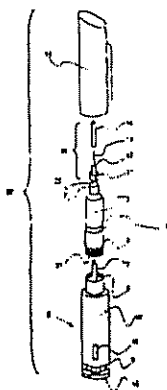
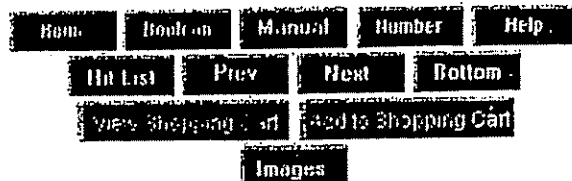


EXHIBIT I

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**US PATENT & TRADEMARK OFFICE**
PATENT FULL TEXT AND IMAGE DATABASE

(2 of 33)

United States Patent

6,146,361

DiBiasi, et al.

November 14, 2000

Medication delivery pen having a 31 gauge needle

Abstract

A *needle* assembly for a medication delivery pen having a 31 gauge *needle* cannula that reduces penetration force during an injection process resulting in less pain to the patient without causing any loss in performance or structural integrity.

Inventors: **DiBiasi; Michael D.** (West Milford, NJ); **Harbin; Elizabeth A.** (Wayne, NJ); **West; Robert E.** (Morristown, NJ)

Assignee: **Becton Dickinson and Company** (Franklin Lakes, NJ)

Appl. No.: 721368

Filed: September 26, 1996

Current U.S. Class:

604/232; 604/272

Intern'l Class:

A61M 005/00

Field of Search:

604/232,233,234,272,207,208,211,187

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EXHIBIT J

United States Patent [19]**Sams**[11] **Patent Number:** 4,936,833[45] **Date of Patent:** Jun. 26, 1990[54] **CARTRIDGE-HOLDER ASSEMBLY FOR MEDICATION DISPENSING UNIT**[75] **Inventor:** Bernard Sams, London, England[73] **Assignee:** Hypoguard (UK) Limited, Woodbridge, England[21] **Appl. No.:** 237,147[22] **Filed:** Aug. 26, 1988**Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 205,198, Jun. 10, 1988, Pat. No. 4,865,591, which is a continuation-in-part of Ser. No. 81,241, Aug. 4, 1987, abandoned.

[51] **Int. Cl.³** A61M 5/24[52] **U.S. Cl.** 604/232; 604/208; 604/209; 604/220; 222/391[58] **Field of Search** 604/68, 72, 208-210, 604/218, 220, 232, 234, 197; 222/325, 340, 391[56] **References Cited****U.S. PATENT DOCUMENTS**

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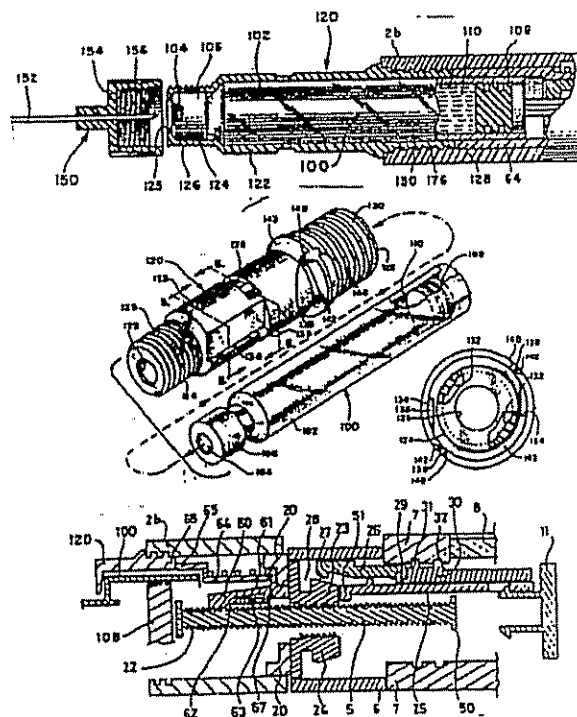
22140 10/1961 German Democratic Rep. 222/391

Primary Examiner—Martin P. Schwadron
Assistant Examiner—Allen J. Flanigan
Attorney, Agent, or Firm—William Brinks Olds Hofer Gilson & Lione

[57] **ABSTRACT**

A cartridge assembly for a syringe-type medication dispensing unit includes a cartridge having a cartridge body with first and second ends. A pierceable membrane is mounted at the first end and a piston is mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston. A cartridge holder receives the cartridge and defines first and second ends. The first holder end defines a central opening and an external thread for mounting a double-ended needle. The second holder end defines an external thread for securing the holder to a medication dispensing unit and an actuating shoulder. The holder frictionally engages the cartridge to form an assembly which can be handled as a single modular unit with the cartridge held securely in the holder by frictional engagement.

23 Claims, 6 Drawing Sheets



SAN00762258

EXHIBIT K

US005554125A

United States Patent [19]**Reynolds**[11] **Patent Number:** **5,554,125**[45] **Date of Patent:** **Sep. 10, 1996**[54] **PREFILLED VIAL SYRINGE**[76] **Inventor:** David L. Reynolds, 305 Knowlton Road, P.O. Box 600, (Knowlton) Lac Brome, Quebec, Canada, JOE 1V0[21] **Appl. No.:** 245,132[22] **Filed:** May 17, 1994**Related U.S. Application Data**

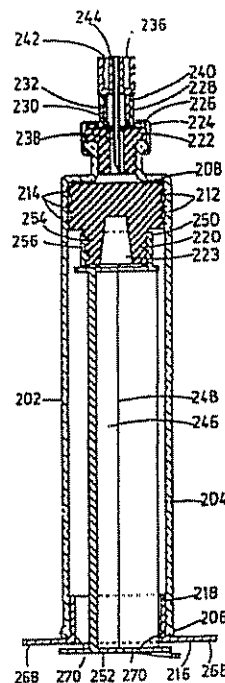
[63] Continuation-in-part of Ser. No. 791,399, Nov. 16, 1991, Pat. No. 5,364,369, which is a continuation-in-part of Ser. No. 437,203, Nov. 16, 1989, Pat. No. 5,137,527, which is a continuation-in-part of Ser. No. 72,015, Jul. 8, 1987, Pat. No. 4,886,495.

[30] **Foreign Application Priority Data**Nov. 14, 1990 [GB] United Kingdom 9024710
May 17, 1993 [GB] United Kingdom 9310084[51] **Int. Cl.⁶** A61M 5/00[52] **U.S. Cl.** 604/187; 604/200; 604/201; 604/203[58] **Field of Search** 604/82, 87, 88, 604/89, 91, 92, 191, 187, 200, 201, 203, 204, 205, 411, 413, 414, 415, 416, 905, 232, 218, 220[56] **References Cited****U.S. PATENT DOCUMENTS**3,074,541 1/1963 Roehr 604/201
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Primary Examiner—Corrine M. Maglione**Assistant Examiner**—N. Kent Gring[57] **ABSTRACT**

A prefilled syringe for one or two component medicaments is based upon the use of a vial containing a medicament or one component of a medicament, the vial having an open bottom closed by a piston. When a flexible extension of the piston is coupled with a tubular plunger, and an adaptor cap having an internal needle and an external connection for a needle is placed over a cap of the vial, the latter is converted into a prefilled syringe. The open bottom of the vial is configured so as not to interfere with handling of the vials by conventional vial sterilizing, filling and capping machinery, and may be formed so as to provide an internal shoulder which will secure a piston retention member.

14 Claims, 9 Drawing Sheets

SAN00762354

EXHIBIT L



US005549575A

United States Patent [19]**Giambattista et al.**[11] **Patent Number:** **5,549,575**[45] **Date of Patent:** **Aug. 27, 1996**[54] **CARTRIDGE RETAINER ASSEMBLY FOR MEDICATION DELIVERY PEN**[75] **Inventors:** Lucio Giambattista, East Hanover, Theodore Siuta, Brant Beach, both of N.J.[73] **Assignee:** Becton Dickinson and Company, Franklin Lakes, N.J.[21] **Appl. No.:** 304,953[22] **Filed:** Sep. 13, 1994[51] **Int. Cl.**⁶ A61M 5/00[52] **U.S. Cl.** 604/232; 604/206; 604/241[58] **Field of Search** 604/232, 234, 604/206-211, 240-243, 181, 187, 199-201, 71, 72, 131-136, 139, 218, 905[56] **References Cited****U.S. PATENT DOCUMENTS**

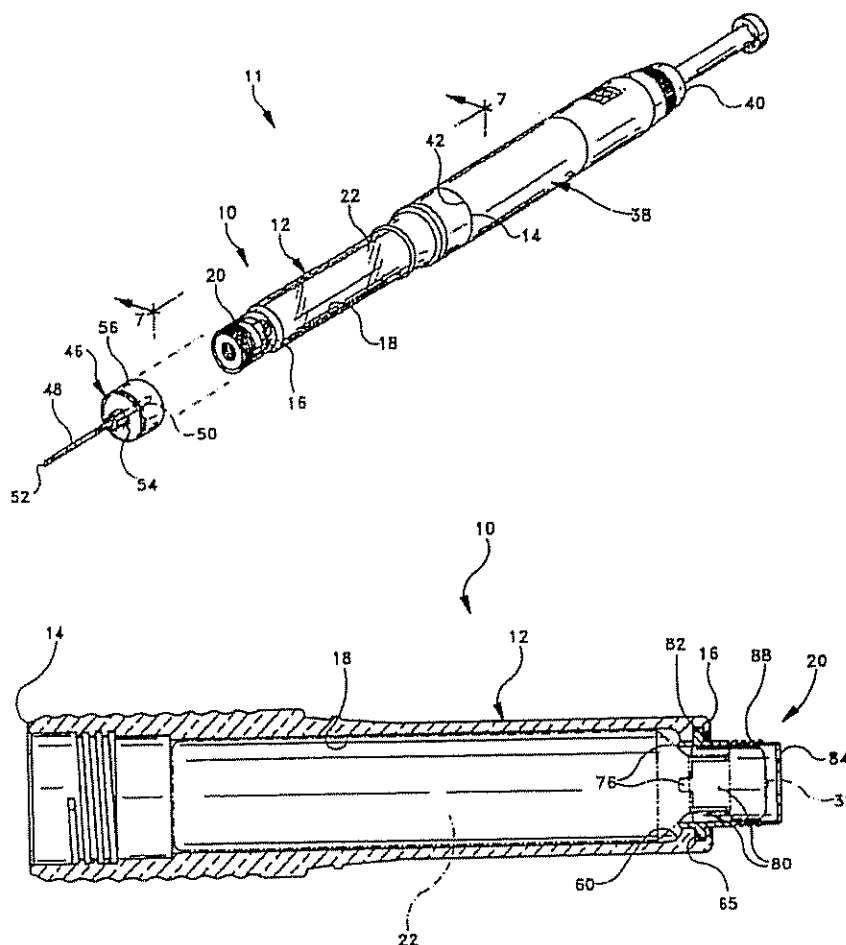
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Primary Examiner—John D. Yasko
Assistant Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Alan W. Fiedler

[57] **ABSTRACT**

A cartridge retainer assembly is provided for a medication delivery pen. The cartridge retainer assembly includes a generally tubular body for receiving, supporting and accurately positioning the body and shoulder portions of a cartridge of medication. A needle mounting collar is floatably mounted to the body of the cartridge retainer assembly for receiving the neck, rubber septum and crimped metallic sleeve of the cartridge. The needle mounting collar will float into a position which compensates for eccentricities and dimensional variations of the cartridge.

9 Claims, 5 Drawing Sheets

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ALL STATE LEGAL 800 722 0510

EXHIBIT M



US005137511A

United States Patent [19]
Reynolds

[11] Patent Number: **5,137,511**
 [45] Date of Patent: **Aug. 11, 1992**

[54] SYRINGE

- [75] Inventor: David L. Reynolds, Montreal, Canada
 [73] Assignee: Duoject Medical Systems Inc., Lac Brome, Canada
 [21] Appl. No.: 437,203
 [22] Filed: Nov. 16, 1989

Related U.S. Application Data

- [63] Continuation-in-part of Ser. No. 72,015, Jul. 8, 1987, Pat. No. 4,886,495.
 [51] Int. Cl. A61M 5/00
 [52] U.S. Cl. 604/88; 604/416; 604/413; 604/191
 [58] Field of Search 604/82, 87, 88, 89, 604/91, 92, 191, 200, 201, 413, 414, 416

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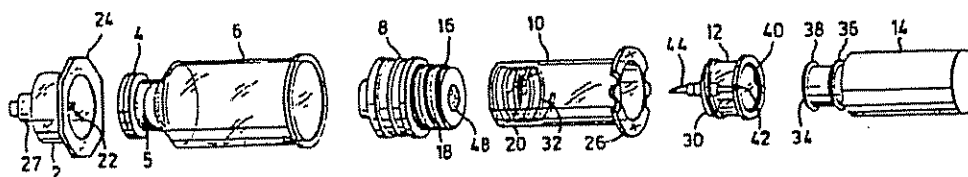
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Primary Examiner—Stephen C. Pellegrino
 Assistant Examiner—Ralph A. Lewis

[57] ABSTRACT

A prefilled syringe for one or two component medications is based upon the use of a vial containing a medicament or one component of a medicament, the vial having an open bottom closed by a piston. When a flexible extension of the piston is coupled with a tubular plunger, and an adaptor cap having an internal needle and an external connection for a needle is placed over a cap of the vial, the latter is converted into a prefilled syringe. The piston may have an axial passage closed by a resealable septum, so that a separate diluent stored in a flexible capsule may be introduced into the vial through the piston by a double ended needle mounted on a further cap applied to the capsule, the further cap being coupled within the tubular interior of the plunger so that the double ended needle penetrates the septum in the piston. The capsule is pushed forward onto the double ended needle when its contents are to be expelled into the vial. The capsule and its cap are then removed and discarded. In an alternative arrangement, the cap of the capsule is coupled to the adaptor cap and the diluent introduced into the vial through a closure secured by the cap of the vial, after which the capsule is removed from the plunger and the latter is coupled to the piston.

11 Claims, 8 Drawing Sheets



SAN00762289

EXHIBIT N



McDonnell Boehnen Hulbert & Berghoff LLP

300 South Wacker Drive 312 913 0001 phone
Chicago, Illinois 60606-6709 312 913 0002 fax
www.mbhbl.com

September 6, 2006

VIA FACSIMILE

Stephen J. Vitola
White & Case LLP
1155 Avenue of the Americas
New York, New York 10036-2787

Re: Novo Nordisk A/S. v. sanofi-aventis et al.
Civil Action No. 05-00646 SLR

Dear Stephen:

I am writing to correct the misstatements of fact contained your September 1, 2006 letter and confirm the September 1 agreements between Novo and Aventis.

First, it is our recollection that when the parties agreed to extend the deadline to amend pleadings from August 1 to September 1, the extension was specifically requested to allow each party sufficient time to discover facts necessary to support amended pleadings through both document review and depositions. Regardless of Novo's contrary recollection regarding this agreement, however, your continued failure to provide any dates when Novo's witnesses will be available to be deposed is not acceptable. Indeed, even if Novo's witnesses were unavailable to be deposed in August, Novo should have at least provided possible deposition dates in September. As it stands, over one month has passed since Novo was served with deposition notices, and Novo has not provided a single possible day when the depositions could occur.

Second, the assertion that Aventis delayed providing its amended answer to Novo is disingenuous. On Tuesday, August 29, after it was clear that Novo was not going to provide any witnesses during August or even any dates when witnesses would be available, we advised you that Aventis intended to file amended pleadings and sought Novo's consent for the filing. Upon being informed that Novo would not consent to the filing until it had reviewed the amended pleading, we promptly completed drafting the amended pleading and forwarded it to you for review.

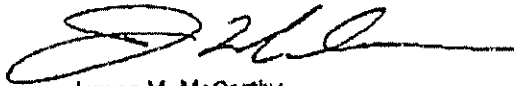
SEP-06-06 09:25 From: MCDONNELL 3129035570

T-066 P.03/03 Job-062

During our telephone conversations with your office on Friday, September 1, we were informed that Novo was prepared to consent to Aventis's filing on September 1 if Aventis agreed to electronic discovery limitations in the unrelated ITC proceeding between the parties. After Aventis refused to agree to the proposed concessions, Mr. Weingaertner and Mr. Oelke informed us for the first time that Novo would need additional time to review Aventis's amended pleading. Accordingly, we agreed to extend the deadline to amend pleadings from September 1 to September 8. We also emphasized that Aventis would not consider any side deals in connection with Aventis's proposed stipulation for leave to file an amended pleading.

In view of the new September 8 deadline, we would appreciate receiving Novo's decision by the close of business on September 7, 2006. We also look forward to receiving dates when Novo's 30(b)(6) witness and Mr. Began will be available to be deposed.

Sincerely,



James M. McCarthy
312 935 2359 direct
mccarthy@mbhb.com

JMM/ws

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

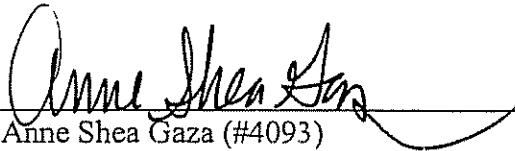
CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2006, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Steven J. Balick, Esquire
John G. Day, Esquire
Lauren E. Maguire, Esquire
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P.O. Box 1150
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I hereby certify that on November 22, 2006, I have sent by Federal Express the foregoing document to the following non-registered participants:

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UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

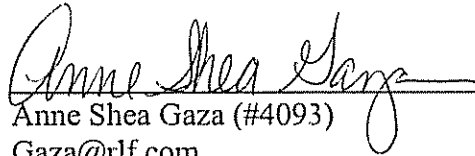
CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2006, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on November 30, 2006, I have sent by Federal Express the foregoing document to the following non-registered participants:

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